Remarks:

Claims 1–17 were previously pending with claim 1 being independent. Claims 1–6, 9, 10, 13, 14, and 17 are presently amended, claims 7–8, 12, and 15–16 are cancelled, and new claims 18–21 are added. Therefore, claims 1–6, 9–11, 13–14, and 17–21 are currently pending with claims 1, 18, and 20 being independent.

In the Office Action dated July 5, 2005 ("OA"), a new oath or declaration was required because the originally-filed oath or declaration did not identify the citizenship of the inventor. Claims 7, 12–13, and 15–16 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 2, 4, 7–11, 13, and 15–17 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 3–5, 9, 11, and 12 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kraftson, U.S. Patent No. 6,151,581. Claims 2, 8, 10, and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraftson in view of Oyama, U.S. Patent No. 5,496,175. Finally, Claims 6–7 and 13–16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraftson in view of Official Notice.

The Application Invention

The application invention involves a novel method of enabling a patient to submit medical information directly to the patient's electronic medical record (EMR). A skilled artisan will quickly recognize that an EMR is not just any data record containing any medical information. Also referred to as an "electronic patient record," an EMR includes information submitted by medical professionals, such as doctors and laboratory technicians, and is used by the medical professionals to diagnose and treat the patient. Thus, an EMR is an electronic version of the patient's medical "file" that contains information personal to the patient and that is used by medical professionals to treat the

patient.

As explained in the application, the submission of information to a patient's EMR is regulated by privacy laws which require healthcare providers to maintain the privacy of a patient's medical history and thus restrict access to the patient's medical records, including electronic medical records. Thus, healthcare providers are required to limit the manner in which a patient's personal information is added to an EMR database to ensure that only authorized personnel view the information stored in the database. For example, prior art methods of submitting a patient's medical information to an EMR involve a doctor soliciting medical information from the patient, recording the information, and giving the recorded information to a staff member who manually submits the patient's medical information to the EMR.

The application invention improves upon the prior art methods by enabling the patient to add personal medical information to his or her EMR with little or no assistance from a healthcare professional or staff member while preserving the privacy of the EMR database. Notably, the application invention accomplishes this without requiring a re-design of existing EMR database management software or software used by healthcare professionals to access patients' electronic medical records.

Particularly, the method of the invention involves receiving a questionnaire from a patient, wherein the patient has filled out the questionnaire with the patient's pertinent medical information. The questionnaire is then scanned to convert the information on the questionnaire to computer-processable data. The computer-processable data is structured according to a Health Level Seven (HL7) medical data communications protocol and communicated to an EMR interface engine for addition to the patient's personal EMR in an EMR database. The HL7 protocol was developed to enable cross-platform communication of electronic medical record data between computer systems, such as a laboratory computer system and a physician's office computer system. According to the exemplary embodiment of the invention disclosed in the application, the data received from the patient is structured to simulate an HL7 laboratory record to render

it compatible with an EMR interface engine. In other words, the interface engine treats the patient-submitted data as if it were received from a laboratory computer system. The application invention thus builds upon the HL7 protocol—which is already commonly used by physicians' computer systems—by enabling the computer systems to receive medical information directly from a patient and add the information to the patient's electronic medical record.

The patient submits the questionnaire prior to an appointment with the doctor, such as while the patient is in the waiting room on the day of the appointment. The information is scanned and added to the patient's personal EMR nearly instantaneously, as explained above, to enable the doctor to view the information as part of the patient's personal medical record at the appointment. Thus, the invention ultimately saves the doctor time by eliminating the need for the doctor to ask the patient questions about his or her health status, write the questions down, and ask a staff member to add the information to the patient's EMR.

Summary of the Kraftson reference

Kraftson discloses a system and method for the "acquisition, management and processing of patient clinical information and patient satisfaction information received from a group of physician practices to provide practice performance information." (Kraftson, col. 2, lines 52–56). Kraftson uses the information gathered from multiple practices to create statistical summaries of practice results, including effectiveness of treatment, patients' perception of the quality of the healthcare, and costs. (*Id.*, col. 5, lines 23–37, 52–62).

Kraftson discloses using machine-readable survey forms to collect information from both doctors and patients, scanning the survey forms, converting the information on the forms to a pre-determined data format, and storing the data in a database for further processing. (*Id.*, col. 5, lines 1–13; col. 6, lines 1–8). The survey

forms are completed by the patient and the physician "during a treatment session at [the] physician's practice" or after the treatment session. Importantly, the patient's portion of the survey relates exclusively to satisfaction with the physician's services. (*Id.*, col. 6, line 3; col. 11, lines 15–17; col. 12, lines 14–24; tables 1A, 1B; FIGs. 2A–2C).

The information submitted by the patient and the doctor is converted to "data records having a predetermined format." (*Id.*, col. 7, lines 8–9). Note that the information is converted to "data records," *not* medical records. The data records created by the system disclosed in Kraftson are entirely different than medical records. For example, the data records are created according to a format that facilitates statistical analysis of the information, such as storing prescription information in a sub-database separately from other elements of the information. (*Id.*, col. 7, lines 45–53). The data records are not used by a physician during a treatment session, and are never added to a patient's electronic medical record.

Thus, there are several notable differences between the method disclosed in Kraftson and the method of the application invention. First, the method of the application invention receives information from the patient *prior to* a doctor's visit, while the method of Kraftson receives information from the patient *during or after* the doctor's visit. Second, the method of the application invention collects *health status* information from the patient while the method of Kraftson collects *satisfaction* information from the patient. Third, the method of the application invention adds the information collected by the patient into the patient's *personal electronic medical record* for use *during* a doctor's visit, while the method of Kraftson stores the satisfaction information collected from the patient in *data records* for statistical analysis *after* the doctor's visit. Finally, the method of Kraftson *increases* the amount of information the doctor must record during a visit with the patient, while the method of the application invention *reduces* the amount of information the doctor must record during a visit with the patient.

The rejections under 35 U.S.C. § 112

In the Office Action, claims 7, 13, and 15 were rejected under 35 U.S.C. § 112, first paragraph, as reciting limitations that are not supported in the originally-filed specification. Specifically, those claims were rejected for reciting limitations relating to the use of an ASTM protocol. Applicant initially notes that claim 15 has been cancelled, and respectfully asserts that the original disclosure was sufficient to support the limitations of claims 7 and 13. Those skilled in the art will recognize, for example, that an ASTM protocol is used to enable cross-platform communication of electronic medical record data between computer systems in a manner substantially similar to HL7. Therefore, the original disclosure was adequate to enable a skilled artisan to implement the present invention using ASTM.

Section 608.01(l) of the MPEP states:

> In establishing a disclosure, applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it.
>
> Where subject matter not shown in the drawing or described in the description is claimed in the application as filed, and such original claim itself constitutes a clear disclosure of this subject matter, then the claim should be treated on its merits, and requirement made to amend the drawing and description to show this subject matter. The claim should not be attacked either by objection or rejection because this subject matter is lacking in the drawing and description. It is the drawing and description that are defective, not the claim.
>
> It is, of course, to be understood that this disclosure in the claim must be sufficiently specific and detailed to support the necessary amendment of the drawing and description.

Applicant notes that the specification has been amended to recite that "[i]t will be appreciated that the present invention is not limited to the use of HL7, and those skilled in the art will recognize that other cross-platform data communications protocols, such as a protocol created by the American Society for Testing and Materials (ASTM), may be used in a manner substantially similar to HL7 as described herein." As explained above, this

would have been understood by a skilled artisan from the original disclosure and therefore does not constitute new matter.

In the Office Action, various other dependent claims were rejected under 35 U.S.C. § 112, first and second paragraphs, as failing to comply with the written description requirement and failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are presently cancelled or amended to comply with § 112. Therefore, Applicant believes that all claims presently conform to the requirements of § 112.

The rejection of claim 1 under 35 U.S.C. § 102(b)

In the Office Action, claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Kraftson. Applicant respectfully disagrees and asserts that Kraftson does not teach or suggest each limitation of claim 1. Applicant notes that a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *(Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); MPEP § 2131). Furthermore, the "identical invention must be shown in as complete detail as is contained in the . . . claim." *(Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989); MPEP § 2131).

First, Kraftson does not teach or suggest a method of allowing a patient to have limited input access to their electronic medical record including the step of "sending the formatted data to an assigned location for importing into the patient's medical record," as recited in claim 1. Column 6, lines 10–18 of Kraftson are cited in the Office Action as teaching this limitation. (OA, page 8). This section of Kraftson reads:

> The System further includes a Data Analysis Processor 108 for analyzing the Physician/Patient/Management information according to selected data analysis packages such as Statistical Package for the Social Sciences (SPSS) or SAS, a Report Generation Module 110 for generating formatted reports containing results determined by the Data Analysis Processor 108, and an Outcomes Measurement Module 112 for recording and tracking

performance of the System.

As can be seen, this section discloses analyzing information and generating a "formatted report," but fails to even mention importing data into the patient's electronic medical record. As explained above, a patient's electronic medical record is not a report containing results of an automated data analysis, but rather a private record containing that patient's personal medical information that is viewable by a physician at the time the patient receives care from the physician. Furthermore, Kraftson expressly teaches that the system disclosed in Kraftson generates two kinds of reports: 1) "a periodic report which summarizes general information about a quality level of the practice," and 2) "real time reports in response to physician queries" such as where a physician needs "information comparing the historical data concerning satisfaction of patient treatment in order for the physician to determine where a recently implemented change in treatment regimen improves or decreases patient satisfaction." (Kraftson, col. 8, lines 39–63). These reports are clearly not individual electronic medical records viewable at the time of care, which is further evidenced by Kraftson's disclosure that physicians must "dial up" a report generation module, and receive "periodic practice reports" or "printed reports." (*Id.*, col. 5, lines 12–16).

Furthermore, it would not have been obvious to one of ordinary skill in the art to modify Kraftson to "send formatted data to an assigned location for importing into a patient's medical record." For example, adding information to a patient's medical record must be done in a manner that conforms with the privacy requirements described above, which, prior to Applicant's invention, was done manually with software accessible only by physicians and medical staff. Further yet, Kraftson expressly teaches that the information collected from patients is *satisfaction information*, and that automated analyses of the information are *shared* among physician groups. These teachings are incompatible with the use of electronic medical records, which contain patient records that are maintained in privacy.

Kraftson also fails to teach or suggest a method of allowing a patient to have limited input access to their electronic medical record including the step of "arranging the

data stream into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's medical record" as recited in claim 1. Column 6, lines 5–10 and column 7, lines 3–10 of Kraftson are cited in the Office Action as teaching this limitation. (OA, page 7). These sections of Kraftson merely disclose the general concept of converting information to "data records having a predetermined format." As explained above, converting information to a "data record" is an entirely different matter than "arranging the data stream into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's medical record." For example, Kraftson teaches that the data record format enables automated data analyses to be shared among groups of physicians (Kraftson, col. 7, lines 47–50), which is incompatible with storing the data in the patient's individual medical record.

The rejection of claim 6 under 35 U.S.C. § 103(a)

In the Office Action, claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraftson in view of Official Notice. Particularly, the Examiner asserted that "HL7, ANSI, and ASTM are well known in the art for establishing, transmitting and formatting standards for data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson to accommodate HL7, ANSI, or ASTM protocol standards." Applicant respectfully disagrees, and hereby traverses all instances of Official Notice asserted in the Office action.

Applicant respectfully asserts that the Official Notice asserted in the Office Action is not properly based upon common knowledge. "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." (MPEP 2144.03.A.). The HL7 protocol standard was created to enable cross-platform communication of electronic medical record data between disparate computer systems, such as a laboratory computer

system and a physician's office computer system. HL7 is not adapted to receive information from a patient and add the information directly to the patient's medical record. Thus, it would not have been obvious to one skilled in the art to use HL7 to complete a task it was not adapted to perform.

New claims 18 and 20

New independent claims 18 and 20 are presently added, and each includes limitations that are not taught or suggested by the prior art references of record. Regarding claims 18 and 20, Kraftson does not teach or suggest, for example, "communicating the formatted data to an electronic medical record interface" for the same reasons set forth above in relation to claim 1.

Further regarding claim 18, Kraftson does not teach or suggest "presenting the information to a physician as part of the patient's personal electronic medical record." As explained above in the section titled "[t]he application invention," the method of Kraftson requires the doctor to collect information and request reports based on that information separately from the doctor's existing patient chart or file as evidenced by the fact that the doctor has to "dial up," "receive periodic practice reports," or "printed reports" to view the collected information—this is clearly not how doctor's use patients' medical records. It would not have been obvious to modify Kraftson to add patient-submitted information directly to the patient's electronic medical record because methods of modifying a patient's electronic medical record at the time the invention was made required direct access by a physician or member of the physician's staff. Furthermore, Kraftson teaches away from adding patient-submitted information to a patient's electronic medical record because the information collected from a patient not only relates to patient satisfaction, which is not included in a patient's medical record, but also is stored to optimize automatic data analysis, as explained above. These teachings are incompatible with the use of electronic medical records, which contain physician's records that are maintained in privacy.

Further regarding claim 20, Kraftson does not teach or suggest "formatting the machine-processable data with the computer so that the data is in the form of a Health Level Seven laboratory record." First, Kraftson does not mention adding information to a patient's electronic medical record, using a Health Level Seven protocol, or a laboratory record. Furthermore, Kraftson teaches away from adding patient-submitted information to a patient's electronic medical record because the information collected from a patient not only relates to patient *satisfaction*, which is not included in a patient's medical record, but also is stored to optimize automatic data analysis, reports of which are shared between groups of physicians. These teachings are incompatible with the use of electronic medical records, which contain physician's records that are maintained in privacy.

Also regarding claim 20, Kraftson does not teach or suggest "presenting the patient's personal electronic medical record to the physician during the patient's visit with the physician, wherein the electronic medical record includes the information from the printed form." As explained previously, Kraftson expressly teaches collecting information from a patient *during* or *after* a treatment session, therefore such information could not be presented to the physician as part of the patient's electronic medical record during the visit. Furthermore, Kraftson teaches away from presenting the patient-submitted information during the visit because the information relates to the patient's satisfaction with the doctor's services, which the patient cannot assess until the visit is complete.

For at least the reasons set forth above, applicant respectfully submits that claims 1–6, 9–11, 13–14, and 17–21 are now in allowable condition and requests a Notice of Allowance. In the event of further questions, the Examiner is urged to call the undersigned. Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

Respectfully submitted,

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